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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,294	12/19/2001	Suzie Hwang Pun	CTCH-P014	9341

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EXAMINER	
MAIER, LEIGH C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/021,294	PUN ET AL.	
	Examiner	Art Unit	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-7,11-18,20,21,23 and 26-42* is/are pending in the application.

4a) Of the above claim(s) *20 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-7,11-18,20,21,23 and 26-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 20, 2006 has been entered.

Claims 5, 14-17 and 27 have been amended. Claims 22, 24 and 25 are canceled. Claims 29-42 are newly submitted. Claims 5-7, 11-18, 20, 21, 23 and 26-42 are pending. Claims 20 and 21 remain withdrawn from consideration at this time. Any rejection or objection not expressly repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The examiner has reviewed the prosecution in co-pending (now allowed) S.N. 10/021,312. It is noted that the composition claims and product claims were restricted in that case, and no composition claims were allowed in the case. The double patenting rejection is therefore withdrawn.

Claim Rejections - 35 USC § 112

Claims 5-7, 11-18, 23 and 26-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in

the relevant art that Applicant, at the time the application was filed, had possession of the claimed invention.

Claim 5 has been amended to require that "at least one host/guest moiety [is] at a terminus of the complexing agent." Applicant cites a pictorial representation of the complexing agent at page 42 of the specification and the examples as support for this limitation. Regarding the pictorial representation, without further discussion/description, the examiner does not interpret this schematic drawing as requiring that the guest be necessarily at the terminus. It does appear to require that the entity that acts as a guest must be attached in some way to the PEG/polymer component. This would be consistent with the alleged mode of binding of Triton X-100 with cyclodextrin. (See discussion below.)

Claim Rejections - 35 USC § 102

Claims 5-7, 12-18, and 23, 26 and 27 are again rejected under 35 U.S.C. 102(e) as being anticipated by WOLFF et al (US 6,740,643), as set forth in the previous Office action. New claims 29-32 and 34-41 are included in this rejection.

The claims have been amended as discussed above.

WOLFF discloses several compositions comprising a cyclodextrin-containing polymer, plasmid DNA and a complexing agent, as discussed in the previous Office action. Example 6 comprises a composition including a polymer containing cyclodextrins in the side chains, plasmid DNA and Triton-X 100 (a PEG ether of octylphenol).

Applicant's arguments filed January 20, 2006 have been fully considered but they are not persuasive. Applicant argues that the reference does not teach a complexing agent comprising "at

least one host/guest moiety at a terminus of the complexing agent." (original emphasis) Applicant cites Tang, a reference that teaches when Triton X-100 (TX) is added to a complex of thiabendazole (TBZ) and β–cyclodextrin (CD), a ternary inclusion complex is formed. When excess TX is added, the TX displaces the TBZ and forms a complex wherein the phenyl ring is pictured as being in the CD cavity. Applicant contends that demonstrates that the complexed moiety is not at the terminus of the complexing agent. This is noted.

Smith et al (J. Incl. Phen., 1991), on the other hand, teaches that, in the absence of TBZ, TX forms a complex with CD wherein the *t*-octyl moiety resides in the CD cavity. See entire reference, particularly section 3.6. Furthermore, Du et al (Supramolec. Chem., 2005) also teaches that TX and CD form a complex wherein "the hydrophobic *tert*-octyl chain tethered with the phenyl groups was entrapped in the cavity." See page 210, 2nd col. The reference further teaches that when bromonaphthalene is added, a ternary complex is formed wherein "the flexible octyl chain" is deformed, and the phenyl group is to some extent nudged outside the cavity. See last section "Steric Considerations ..." at pp 213-214, particularly the sentence bridging these two pages.

Therefore, it appears that in most cases, TX forms a CD complex wherein the *t*-octyl moiety does reside inside the CD cavity, so that the guest group is at the terminus of the complexing agent. The examiner concedes that it is possible, but appears unlikely, that in the Wolff composition the TX could form a Tang-type complex. However, even if that were the case, there is no indication that the "flexible octyl chain" would actually extend outside the cavity.

Claim Rejections - 35 USC § 103

Claims 5-7, 12-18, 23, 26, and 27 are again rejected under 35 U.S.C. 103(a) as being unpatentable over WOLFF et al (US 6,740,643) as set forth in the previous Office action. New claims 29-32 and 24-41 are also included in this rejection.

WOLFF teaches as set forth above. The reference further teaches that a cyclodextrin-containing polymer in combination with an amphiphilic compound results in drug delivery system that may be employed generically for biologically active compounds, such as pharmaceuticals, peptides/proteins, viruses, etc. See col 17, lines 50-52 and col 18, lines 32-47. The reference does not exemplify any other biologically active compounds other than polynucleotides.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute any of the biologically active compounds recited in claim 6 because these agents were expressly suggested by the reference. One of ordinary skill would reasonably expect success in making such a substitution because the reference had taught that this drug delivery system is a general one for biologically active compounds.

Applicant's arguments filed January 20, 2006 have been fully considered but they are not persuasive. Applicant argues only that the reference does not teach a complexing agent comprising "at least one host/guest moiety at a terminus of the complexing agent." (original emphasis) This is addressed above.

Claims 28 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over WOLFF et al (US 6,740,643) as set as applied to claims 5-7, 12-18, 23, 26, 27, 29-32 and 24-41 above and further in view of Gonzalez et al (Bioconj. Chem., 1999).

Wolff teaches as set forth above. The reference does not teach a linear cyclodextrin-containing polymer wherein cyclodextrin moieties are present in the backbone of the polymer. The reference suggests the use of linear polymers but without further description of a particular configuration.

Gonzalez et al (Bioconj. Chem., 1999) teaches linear cyclodextrin-containing polymers wherein cyclodextrin moieties are present in the backbone of the polymer. These polymers have utility for the delivery of macromolecular therapeutics, such as DNA. See entire reference.

It would be obvious to one having ordinary skill in the art at the time the invention was made to modify the Wolff composition by the use of any suitable cyclodextrin-containing polymer. The artisan would be motivated to use the polymer taught by Gonzalez because it is disclosed as being useful for delivery of therapeutic agents. One of ordinary skill would reasonably expect success with this substitution.

Allowable Subject Matter

Claims 11 and 33 are objected to as being dependent upon a rejected base claim (insofar as it requires a "guest" on the complexing agent), but would be allowable if rewritten (with appropriate amendment to obviate new matter rejection) in independent form including all of the limitations of the base claim and any intervening claims.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

Visit the U.S. PTO's site on the World Wide Web at http://**www.uspto.gov**. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more. Information regarding the status of an application may be obtained from the Patent Application Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished application is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

Leigh C. Maier

Leigh C. Maier
Primary Examiner
March 31, 2006